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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,956	06/27/2001	William Michael Lafferty	DIVER1280-14	7268

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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	7

DATE MAILED: 11/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/894,956	LAFFERTY, WILLIAM MICHAEL	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *11-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-10 in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, parent applications 09/636,778 filed 11 August 2000; 09/098,206 filed 16 June 1998; and 08/876,276 16 June 1997 upon which priority is claimed do not provide adequate support under 35 U.S.C. 112 for claims 1-10 of this application. Specifically, the parent applications do not provide support for the instantly claimed screening apparatus comprising: plurality of capillaries held together in an array, interstitial material disposed between adjacent capillaries; and one or more reference indicia formed within the interstitial material. Therefore, the effective filing date for instant Claim 1-10 is the filing date of parent application 09/444,112 i.e. 22 November 1999.

Claim Objections

3. Claim 1 is objected to in the last line because "of" is incorrectly placed between "within" and "the". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 7 is indefinite for the recitation "capillaries are fused together to form the array" because it is unclear whether the recitation is a method step of fusing and because it is unclear what structural limitations are being imposed on the apparatus. It is suggested that the claim be amended to clarify as described in the specification (¶ 29, lines 6-8).

b. Claim 8 is indefinite for the recitation "are formed at intervals" because it is unclear whether the recitation is a method step of forming. It is suggested that the claim be amended to clarify e.g. delete "formed".

c. Claim 9 is indefinite for the recitation "are formed at edges" because it is unclear whether the recitation is a method step of forming. It is suggested that the claim be amended to clarify e.g. delete "formed".

d. Claim 10 is indefinite for the recitation "are formed of glass" because it is unclear whether the recitation is a method step of forming. It is suggested that the claim be amended to clarify e.g. replace "are formed of" with "comprise".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-7 and 10 are rejected under 35 U.S.C. 102(a) as being anticipated by Millstein, L. (WO 99/19711, published 22 April 1999).

Regarding Claim 1, Millstein discloses a sample screening apparatus comprising: a plurality of capillaries (array members, page 11, lines 18-21 and page 12, lines 15-37) held together in an array wherein each capillary comprises at least one wall defining a lumen for retaining a sample; interstitial material (i.e. structural member) disposed between adjacent capillaries; and one or more reference indicial formed within the interstitial material (page 14, line 30-page 15, line 2). Specifically, Millstein disclose an apparatus comprising an array of capillaries (i.e. hollow fibers, page 19, line 19-page 20, lines 35 and Fig. 1) and interstitial material (i.e. structural member, page 14, line 32-page 15, line 2) wherein the interstitial material has therein reference indicia (i.e. positional markers, page 15, line 1).

Regarding Claim 2, Millstein discloses the array wherein each capillary has an aspect ration of between 10:1 and 100:1 (i.e. cross-sectional area of about 1.0 to about 1,000,000μm^2, Claims 14; and a thickness of about 2.5 to bout 1,200 μ, Claim 18).

Regarding Claim 3, Millstein discloses the array wherein each capillary has an aspect ration of between 20:1 and 100:1 (i.e. cross-sectional area of about 1.0 to about 1,000,000μm^2, Claims 14; and a thickness of about 2.5 to bout 1,200 μ, Claim 18).

Regarding Claim 4, Millstein discloses the array wherein each capillary has an aspect ration of between 40:1 and 50:1 (i.e. cross-sectional area of about 1.0 to about 1,000,000μm^2, Claims 14; and a thickness of about 2.5 to bout 1,200 μ, Claim 18).

Regarding Claim 5, Millstein discloses the array wherein each capillary has a length of between 5m m and 10 cm (page 14, lines 22-24).

Regarding Claim 6, Millstein discloses the array wherein the lumen of each capillary has an internal diameter of between 3μ m and 500μ m ((page 20, lines 4-7).

Regarding Claim 7, Millstein discloses the array wherein the plurality of capillaries are fused together to form the array (i.e. affixed, page 21, line 34-page 22, line 4).

Regarding Claim 10, Millstein discloses the array wherein the reference indicia are formed of glass i.e. they are a component of the structural member which is comprised of glass (page 18, line 23-page 19, line 36).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dehlinger (U.S. Patent No. 5,763,263 issued 9 June 1998) in view of Winkler et al (U.S. Patent No. 5,677,195).

Regarding Claim 1, Dehlinger teaches a sample screening apparatus comprising: a plurality of capillaries held together in an array wherein each capillary comprises at least one wall defining a lumen for retaining a sample; and interstitial material disposed between adjacent capillaries (Column 7, line 50-Column 8, line 33) wherein the apparatus comprises subarrays comprising positionally addressable array members (Column 7, lines 25-39 and 56-65) but they do not teach the interstitial material comprises one or more reference indicia.

However, reference indicia within interstitial material of an array was well known in the art at the time the claimed invention was made as taught by Winkler et al who specifically teach that reference indicia are essential for consistent and precise positionally addressable array construction and use (Column 18, line 51-Column 19, line 24). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the reference indicia of Winkler et al in the positionally addressable array of Dehlinger thereby placing reference indicia within the interstitial material of the array for the expected benefits of consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

Regarding Claim 2, Dehlinger teaches the array wherein each capillary has an aspect ration of between 10:1 and 100:1 (i.e. 20-200μ inner diameter and length of 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 3, Dehlinger teaches the array wherein each capillary has an aspect ration of between 20:1 and 100:1 (i.e. 20-200μ inner diameter and length of 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 4, Dehlinger teaches the array wherein each capillary has an aspect ration of between 40:1 and 50:1 (i.e. 20-200μ inner diameter and length of 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 5, Dehlinger teaches the array wherein each capillary has a length of between 5m m and 10 cm (i.e. 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 6, Dehlinger teaches the array wherein the lumen of each capillary has an internal diameter of between 3μ m and 500μ m (i.e. 20-200μ inner diameter, Column 8, lines 3-16).

Regarding Claim 7, Dehlinger teaches the array wherein the plurality of capillaries are fused together to form the array (i.e. bonded or fixed, Column 8, lines 17-27).

Regarding Claims 8 and 9, Dehlinger teaches their array of subarrays provides a positionally addressable device (Column 4, line 65-column 5, line 4) but they do not teach the interstitial material comprises one or more reference indicia formed at intervals (Claim 8) and formed at edges (Claim 9). However, reference indicia within interstitial material of an array was well known in the art at the time the claimed invention was made as taught by Winkler et al (Column 18, line 51-Column 19, line 24). And Winkler et al specifically teach arrays comprising reference indicia at formed at array intervals (i.e. local) and at edges (i.e. global) wherein the local and/or global indicia are essential for exact positioning and detecting of array addresses (Column 19,lines 4-39). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the local and/or global reference indicia of Winkler et al in the positionally addressable array of Dehlinger and to place the reference indicia at intervals and/or at edges of the array for the expected benefits of consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

Regarding Claim 10, Dehlinger teaches the array wherein capillary array comprises glass (Column 7, lines 40-47; Column 8, lines 34-44; and Column 13,line 56-Column 14, line 32) but they do not teach the array comprises reference indicia formed of glass. Winkler et al teach a similar array wherein the array comprises glass (Column 6, lines 49-60 and Column 14, lines 45-55) and they teach the array comprises reference indicia (Column 19, lines 4-24). Therefore, the reference indicia of Winkler are formed of glass as claimed. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the glass array of Dehlinger by forming reference indicia on the array as taught by Winkler et al for the expected benefits of consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

10. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Millstein, L. (WO 99/19711, published 22 April 1999) in view of Winkler et al (U.S. Patent No. 5,677,195).

Regarding Claims 8 and 9, Millstein teaches the sample screening apparatus comprising: a plurality of capillaries (array members, page 11, lines 18-21 and page 12, lines 15-37) held together in an array wherein each capillary comprises at least one wall defining a lumen for retaining a sample; interstitial material (i.e. structural member) disposed between adjacent capillaries; and one or more reference indicial formed within the interstitial material (page 14, line 30-page 15, line 2) but Millstein does not teach the interstitial material comprises one or more reference indicia formed at intervals (Claim 8) and formed at edges (Claim 9). However, reference indicia within interstitial material of an array was well known in the art at the time the claimed invention was made as taught by Winkler et al (Column 18, line 51-Column 19, line 24). Winkler et al specifically teach arrays comprising reference indicia formed at array intervals (i.e. local) and at edges (i.e. global) wherein the local and/or global indicia are essential for exact positioning and detecting of array addresses (Column 19,lines 4-39). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the local and/or global reference indicia of Winkler et al to the array of Millstein and to place the reference indicia at intervals and/or at edges of the array for the expected benefits of consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

Double Patenting

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. Claims 1-10 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10 of copending Application No. 09/790,321. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
November 13, 2002